

### DEPARTMENT OF THE NAVY

BUREAU OF MEDICINE AND SURGERY 2300 E STREET NW WASHINGTON DC 20372-5300

Canc: Apr 2013

**BUMEDNOTE 3440 BUMED-M3** 

25 Apr 2012

### **BUMED NOTICE 3440**

From: Chief, Bureau of Medicine and Surgery

Subj: NAVY MEDICINE EMERGENCY PREPAREDNESS LOGISTICAL GUIDANCE FOR CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR PROGRAM

Ref:

- (a) DoDI 6200.03 of March 5, 2010
- (b) BUMEDINST 3440.10
- (c) BUMEDINST 6710.62A
- (d) NAVMED P-5132 of 3 Jan 2008

- Encl: (1) Acronyms
  - (2) Chemical, Biological, Radiological, and Nuclear H199 Assemblage (Minimal Allowance) List
  - (3) Chemical, Biological, Radiological, and Nuclear Pharmaceuticals Storage Requirements
  - (4) Chemical, Biological, Radiological, and Nuclear Pharmaceuticals Rotation Management
  - (5) How to Gain Chemical, Biological, Radiological, and Nuclear Materials, Pharmaceuticals, and Equipment in Defense Medical Logistics Standard Support-Assemblage Management
- 1. Purpose. To establish policy and guidance at Medical Treatment Facilities (MTF) for the management, storage, distribution, inventory control; and use of specific Chemical, Biological, Radiological, and Nuclear (CBRN) materials, equipment, and pharmaceuticals in support of the Navy Medicine Emergency Preparedness (EP) CBRN program in accordance with references (a) through (d). Enclosure (1) provides a list of acronyms.
- 2. Scope. This notice describes the policies, practices, procedures, and systems for managing the equipment and consumables which support the Navy Medicine EP CBRN program, a component of the Navy Medicine Force Health Protection Emergency Management Program (FHP EMP).
- 3. Background. Properly maintained CBRN materials, equipment, and pharmaceuticals ensure that MTFs have the essential resources necessary to respond in the event of a CBRN incident. Supporting these requirements are procurement and maintenance of an adequate stock of CBRN materials, equipment, and pharmaceuticals. Prior to 2008, MTF CBRN equipment and supplies were fielded through the Joint Program Executive Office for Chemical and Biological Defense Joint Program Manager Guardian (JPMG) Installation Protection Program (IPP). As of fiscal year 2011, BUMED Deputy Chief, Medical Operations (BUMED-M3) EP Directorate, now is

responsible for the procurement and distribution of CBRN materials, equipment, and pharmaceuticals to MTFs. BUMED purchases the replacement CBRN materials, equipment, and pharmaceuticals for tier 1 to tier 3 MTFs as delineated in enclosure (2). These items are critical for maintaining mission assurance and continuity of operations for MTF personnel and patients during and immediately following a CBRN event.

- 4. <u>CBRN Materials</u>, <u>Equipment</u>, and <u>Pharmaceuticals Management Program Elements</u>. The MTF Emergency Manager (MEM) at each MTF defined in accordance with reference (a) where equipment is stored is responsible for all CBRN materials and equipment. The Head, Pharmacy Department at each MTF is responsible for safeguarding all CBRN Pharmaceutical Countermeasures (CPCs) dispensed by and used in preventive or curative medicine at MTFs. MTF tier designations and detailed distribution of CBRN materials, equipment, and pharmaceuticals are outlined in reference (b).
- a. <u>Acquisition</u>. BUMED-M3 EP Directorate will work with Naval Medical Logistics Command (NAVMEDLOGCOM) in the standardization of procurement and distribution of required CBRN materials, equipment, and pharmaceuticals. BUMED-M3 EP Directorate will provide the MTFs with CBRN on-hand quantity requirements and program funding to ensure compliance with their tier specific allowances.
- b. <u>Pharmaceuticals</u>. The pharmacy department at each MTF shall create a normal working stock rotation in accordance with enclosure (3) to minimize expiration and sustainment cost. The stock levels in this program are set at established safety levels and shall not be reduced. MTFs shall take appropriate action by contacting their Navy Medicine Region to replace items that become unserviceable. In addition, The Food and Drug Administration (FDA) Shelf Life Extension Program (SLEP), which focuses upon deferring drug replacement costs for date sensitive pre-positioned material, shall be used aggressively to reduce replacement costs. The following CPCs are subject to all of the requirements of the SLEP. In accordance with reference (c), these products should not be returned via reverse distribution service provider until the FDA completes a sample test process and subsequently concludes these products have no useful life:
  - (1) Antidote Treatment Nerve Agent Auto-Injectors (ATNAA) Atropine & 2PAM
  - (2) Convulsant Antidote for Nerve Agent (CANA) Diazepam
  - (3) Ciprofloxacin\*
  - (4) Doxycycline Hyclate\*
  - (5) Potassium Iodide (KI)

- \* Note: Ciprofloxacin (6505-01-273-8650) and doxycycline hyclate (6505-01-505-0146) presently employed in the CBRN H199 Assemblage List (enclosure (2)) are Unit Dose packaged and do not qualify for SLEP. Unit dose material will eventually be phased out and replaced with bottled ciprofloxacin and doxycycline hyclate.
- (6) Extended pharmaceuticals must be recorded in Defense Medical Logistics Standard Support (DMLSS) Assemblage Management (AM) record data module to reflect the revised expiration date and authority for extension. Expired pharmaceuticals may be eligible to be returned utilizing the MTFs contracted reverse distribution service provider. Should there be a product recall, the head of the pharmacy department will notify the responsible party and provide specific return instructions.

#### c. CPCs Storage and Stock Rotation

- (1) CPCs are to be kept in a climate-controlled storage that will meet temperature requirements and provide for the appropriate security requirements, enclosure (4).
- (2) It is mandatory to rotate CPC antibiotics (doxycycline hyclate and ciprofloxacin) with MTF just in time inventory and working stock, enclosure (3).
- (3) To ensure emergency first receivers are protected against the effects of CBRN exposure, the CPCs must be made readily available and appropriate access must be allowed. Note: MTFs maintaining a cache of CPCs for Commander, Navy Installation Command (CNIC) category 1 and 5 personnel (e.g., Emergency Essential and Emergency First Responders), may choose to issue only the ATNAA to CNIC units to allow for immediate accessibility. The CNIC cache of CANA, antibiotics (doxycycline hyclate and ciprofloxacin) and KI will remain under MTF control until authorized to release and distribute. An integrated CPC policy developed between CNIC (units) and their servicing MTFs is an alternative. This policy should address planning for rapid distribution, current threat levels, preparedness activities both pre- and post-incident exposure, distribution plan, provisions for security and access, storage requirements, storage location, administration and handling of CPCs, and maintenance roster of CNIC category 1 and 5 personnel.

### d. Materials and Equipment

(1) CBRN materials and equipment will be stored in secure, environmentally protected areas that are immediately available should an emergency dictate its use. These items can be stored off-site, but must be readily accessible even during inclement weather. The actual location of the material must be entered into the DMLSS-AM. Material Management Department (MMD) must ensure that all CBRN materials have proper and accessible storage for future use and ease of rotation.

- (2) Calibration kits, batteries, and power adaptors will be maintained by the MTF's Biomedical Equipment Maintenance Division (BIOMED). Hazardous Material (HAZMAT) Locker and Material Safety Data Sheets will be used as required for items identified as HAZMAT.
- (3) The equipment stockpile items will be considered to have an extended shelf-life and shall not be discarded based on a manufacturer's recommended expiration date without the approval of BUMED-M3 EP Directorate.

### e. Receipt and Inventory Management

- (1) MMD and BIOMED will assist the MEM in ensuring that all CBRN equipment are received in accordance with reference (d) and properly gained in DMLSS-AM in accordance with enclosure (5).
- (2) The MEM is responsible for gaining the CBRN materials in the DMLSS-AM using the CBRN Assemblage List. The MEM can monitor the "on hand" level by running the "Assemblage Status Rollup Report." This status report will be monitored remotely by the Navy Medicine Region and BUMED-M3 EP Directorate utilizing the Joint Medical Asset Repository (JMAR). Enclosure (5) is provided as the step-by-step procedure on how to gain CBRN materials, equipment, and pharmaceuticals in DMLSS-AM. At the minimum, the following information must be provided when gaining CBRN materials, equipment, and pharmaceuticals into the DMLSS-AM record data module:
  - (a) Location
  - (b) Sub Location
  - (c) On-Hand Qty
  - (d) Strat State
  - (e) Product Number
  - (f) Lot Number (if applicable)
  - (g) Manufacturer
  - (h) Manufacture Date
  - (i) Expiration Date

- (3) At the minimum, quarterly inventory must be conducted using DMLSS-AM physical inventory module and recorded data must be updated as needed. Failure to conduct quarterly inventory in DMLSS-AM will result to inaccurate information reported in the JMAR.
- f. <u>Sustainment Management</u>. Proper implementation and sustainment of CBRN materials, equipment, and pharmaceuticals are a shared responsibility between the MTF, Navy Medicine Regions, and BUMED M3 EP Directorate. BUMED-M3 EP Directorate will establish the life cycle replacement plan for all CBRN materials, equipment, and pharmaceuticals using the information reflected in JMAR. The MEMs via their Navy Medicine Region shall identify material deficiencies and prioritize resource requirements for sustainment of CBRN materials, equipment, and pharmaceuticals, including replenishment of consumables, spare parts, and maintenance not performed by MTF BIOMED. Normal replenishment of day-to-day consumables under the CBRN H199 assemblage, such as batteries, tapes, and sieve packs for Joint Chemical Agent Detectors will be funded by the MTF.
- g. <u>Purchase Validation and Authorization Process</u>. Upon the identification of CBRN material purchase needs, MEMs will submit a DD Form 1149, Requisition and Invoice/Shipping Document via their respective Navy Medicine Region for all CBRN requests. Upon approval, Navy Medicine Region will authorize funding via a funding authorization document to the MTF for procurement.
- h. Equipment Maintenance. BUMED-M3 EP Directorate maintains cognizance over MTF based CBRN preparedness and response policy. NAVMEDLOGCOM has oversight of the medical material equipment and maintenance programs for Navy Medicine. NAVMEDLOGCOM will establish the policies and procedures for EP CBRN materials, equipment, and maintenance management to ensure uniform guidelines for all BUMED MTFs. Policies and procedures outlined in this document are specific to Navy Medicine EP CBRN equipment. MTFs are expected to follow the Equipment Management guidelines outlined in reference (d).
- (1) MEM will ensure that all CBRN equipment is properly cleaned and stowed by users after training sessions, and that proper, periodic maintenance is performed.
- (2) BIOMED will ensure the maintenance plans and procedures in DMLSS are updated specific to the equipment's make and model based on manufacturer's specification or guidance provided from NAVMEDLOGCOM. BIOMED is responsible for ensuring that scheduled maintenance is performed on all maintenance significant CBRN equipment, quarterly perform visual material inspection and inventory, and to quarterly review the current guidance to ensure the activity can meet program requirements.

- (3) Additional equipment and maintenance support inquiries shall be directed to BUMED-M3 EP Directorate.
- 5. <u>Disposal of Equipment</u>. Disposal of CBRN equipment or materials that have been removed or replaced from the authorized H199 Assemblage List may be disposed of following the guidance found in reference (d). Required equipment or materials items maintained at levels above the H199 Assemblage allowance levels will not be deemed "excessive' and will not be considered for disposal.

### 6. Logistics Management Information System

- a. DMLSS-AM module will be the system of choice for managing this program.
- b. <u>JMAR</u>. As CBRN materials, equipment, and pharmaceuticals are entered into DMLSS-AM, inventory data will automatically be uploaded into JMAR at predetermined intervals. Reports can be generated by the Navy Medicine Region or MTFs and will be viewable via dashboard by the MTF, Navy Medicine Region, BUMED, and Assistant Secretary of Defense for Health Affairs.

### 7. Reporting Requirements

- a. <u>BUMED-M3 EP Directorate</u>. Shall develop the Navy Program Objective Memorandum regarding financial requirements for the Emergency Management Program for all Budget Submitting Office (BSO) 18 facilities.
  - b. MTFs. MTF stockpiles will be inventoried as follows:
- (1) The MEM will conduct an annual 100 percent wall-to-wall inventory of CBRN equipment, materials, and pharmaceuticals. In addition, the MEM shall perform quarterly walk-through inspections, in accordance with reference (d).
- (2) MTFs will provide a CBRN inventory report to BUMED-M3 EP Directorate via their respective Navy Medicine Region by 31 March of each year unless directed otherwise.
- 8. Cancellation Contingency. Retain this notice until incorporated into reference (b).

### 9. Forms and Reports

a. DD Form 1149 (July 2006), Requisition and Invoice/Shipping Document is available electronically at http://www.dtic.mil/whs/directives/infomgt/forms/index.htm.

b. The reporting requirements for this instruction are exempt from reports control in accordance with Part IV, paragraph 7g of SECNAV M-5214.1 of December 2005.

M. L. NATHAN

Distribution is electronic only via the Navy Medicine Web site at: <a href="https://www.med.navy.mil/directives/Pages/default.aspx">https://www.med.navy.mil/directives/Pages/default.aspx</a>

### BUMEDNOTE 3440 25 Apr 2012

### **ACRONYMS**

AM Assemblage Management

ATNAA Antidote Treatment Nerve Agent Auto-Injectors
BIOMED Biomedical Equipment Maintenance Division

BMET Biomedical Equipment Technician

BSO Budget Submitting Office

CANA Convulsant Antidote for Nerve Agent

CBRN Chemical, Biological, Radiological, and Nuclear

CNIC Commander, Navy Installation Command
CPC CBRN Pharmaceutical Countermeasures
DMLSS Defense Medical Logistics Standard Support

EP Emergency Preparedness

FDA Food and Drug Administration

FHP EMP Force Health Protection Emergency Management Program

HAZMAT Hazardous Material

IPPInstallation Protection ProgramJMARJoint Medical Asset RepositoryJPMGJoint Program Manager Guardian

KI Potassium Iodide

MEM MTF Emergency Manager

MMD Material Management Department
MTF Medical Treatment Facilities

NAVMEDLOGCOM Naval Medical Logistics Command

SLEP Shelf Life Extension Program

# CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR PHARMACEUTICALS STORAGE REQUIREMENTS

CBRN Pharmaceutical	Storage Requirements
Ciprofloxacin	59-86°F [15-30°C]; protect from light. If any capsules have
Doxycycline Hyclate	melted make the assumption the product is unsuitable for use.
Potassium Iodide	59-86°F [15-30°C]; protect from light; protect from freezing.
Antidote Nerve Agent Auto-	Items exposed to high temperatures above stated ranges should be
Injectors (Atropine/2-PAM	reported to your Service Medical Logistics Activity for possible
Chloride)	potency testing in the FDA SLEP program. Mrs. Etta Ingram,
Convulsant Antidote for Nerve	Navy SLEP Program Manager – 301.619.3085.
Agent (CANA)*	
	* Note: CANA is a Schedule IV controlled substance, proper accountability must be maintained and applicable security measures must be kept.

## CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR PHARMACEUTICALS ROTATION MANAGEMENT

CBRN Pharmaceutical	Rotation Management
Ciprofloxacin	Rotate with just-in-time inventory. In the event of expiration use
Doxycycline Hyclate	MTFs contracted reverse distributor.
Antidote Nerve Agent Auto-	Register these products in the web-based Tri-Service Shelf Life
Injectors (Atropine & 2-PAM	Extension Program at <a href="http://iasmid.dmsb.army.mil">http://iasmid.dmsb.army.mil</a> . Manage your
Chloride)	inventory, lot numbers, sample request, test results and relabeling
Convulsant Antidote for Nerve	in the web-based program. The FDA will conduct sample test of
Agent (CANA)	the product. Results of the test may extend the material to the new
Potassium Iodine	expiration date only if that materiel has been properly stored in
	accordance with the manufacturer's specifications. If the life of
	the product is extended, relabeling must be in compliance with the
	original manufacturer or distributor's FDA-approved
	specifications. Relabeling is an automated process as long as the
	material is listed in the web-based SLEP program.

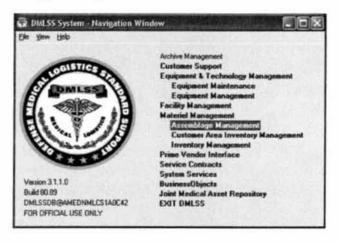
# HOW TO GAIN CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR MATERIALS, PHARMACEUTICALS, AND EQUIPMENT IN DEFENSE MEDICAL LOGISTICS STANDARD SUPPORT-ASSEMBLAGE MANAGEMENT

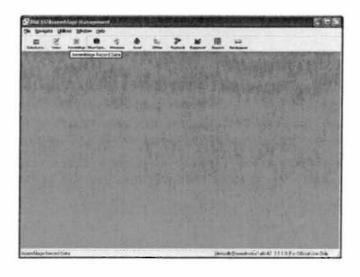
BUMED's global visibility of chemical, biological, radiological, and nuclear (CBRN) material, pharmaceuticals, and equipment, including inventory (on-hand quantity and expiration dates) will be through the Joint Medical Asset Repository (JMAR). It is imperative that MTFs keep an accurate inventory of the CBRN material, pharmaceuticals, and equipment and the Defense Medical Logistics Standard Support-Assemblage Management (DMLSS-AM), because DMLSS-AM will feed JMAR.

#### ASSUMPTIONS:

- 1. CBRN H199 AMAL is already loaded in DMLSS
- 2. The site is aware of their Tier level.

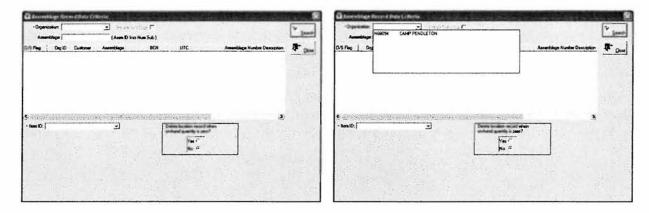
Open the DMLSS Assemblage Management module



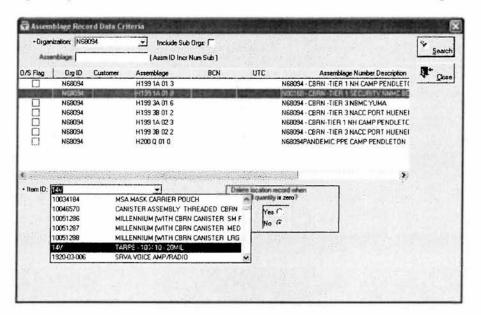


### GAINING CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR MATERIAL

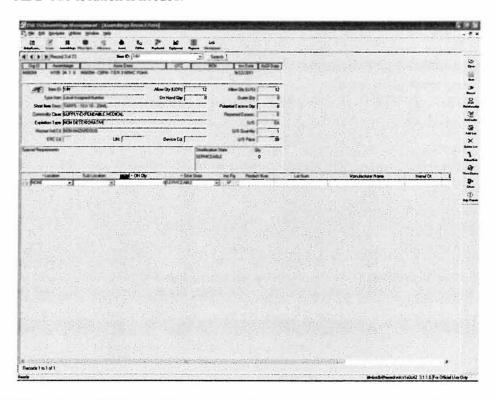
From Assemblage Record Data Criteria Window, SELECT the appropriate organization.



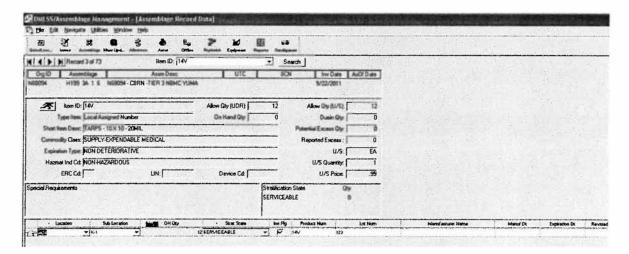
Then highlight the desired assemblage to update and pick the item to be updated. If the entire assemblage requires updating, then pick the first record and scroll to the next record as the item is updated.



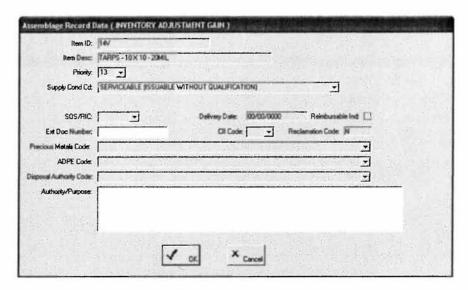
Double check if the correct item is pulled. To add LOCATION, double click inside the field below "Location." ADD Sub location if needed.



Update or GAIN an item by filling out the location, sub location, and on-hand quantity.



When quantity is entered, the below window will appear. Enter the appropriate information and click OK, then select the appropriate GAIN TYPE and click OK.

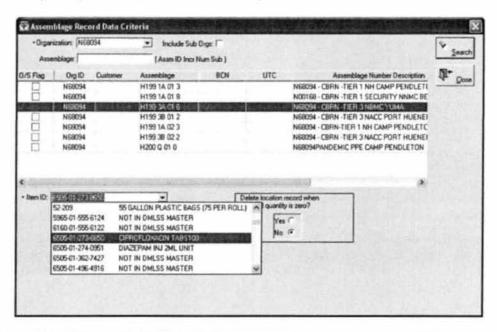


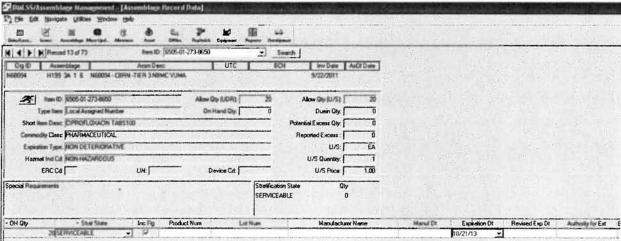


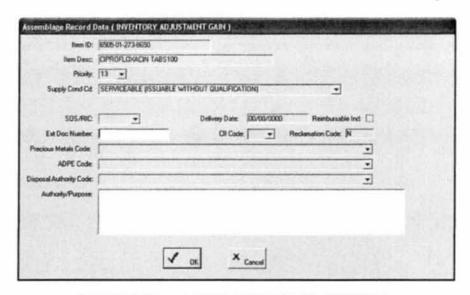
Enter the rest of the item's information: product number, lot number, manufacturer, mfr data and expiration date (if available).

### GAINING CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR PHARMACEUTICALS

From Assemblage Record Data Criteria Window, SELECT the appropriate organization. Highlight the desired assemblage to update and pick the item to be updated.







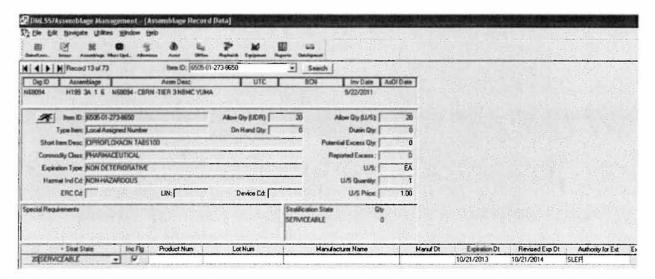


Enter the rest of the item's information: product number, lot number, manufacturer, mfr data and expiration date (MANDATORY).

Additionally, CBRN pharmaceuticals must be entered in the Shelf Life Extension Program (SLEP): <a href="https://slep.dmsbfda.army.mil">https://slep.dmsbfda.army.mil</a>.

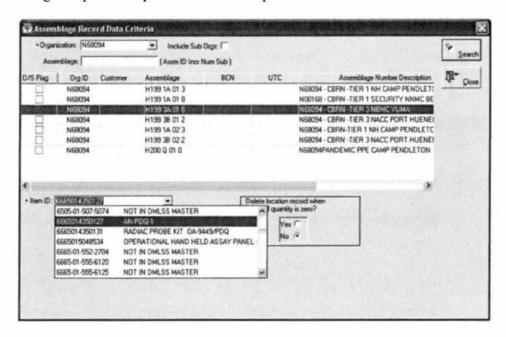
DoD/FDA will notify the sites when the pharmaceuticals become candidates for testing. Additional notification from NAVMEDLOGCOM may follow. The MTF is responsible for sending the pharmaceuticals to the appropriate FDA addresses.

Once FDA testing result is received and the candidate pharmaceutical is authorized for extension, the item's "Revised Exp Dt" and "Authority for Ext" must be updated. Actual Expiration Date information must remain the same.



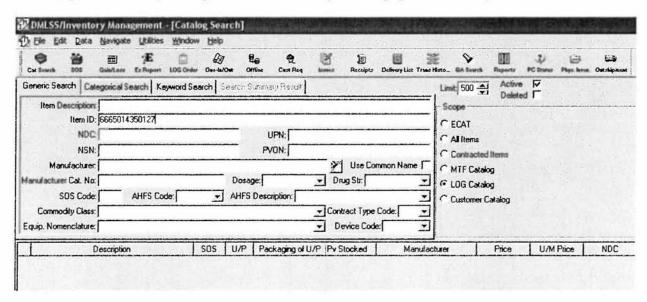
### GAINING CHEMICAL, BIOLOGICAL, RADIOLOGICAL, AND NUCLEAR EQUIPMENT

From Assemblage Record Data Criteria Window, SELECT the appropriate organization. Highlight the desired assemblage to update and pick the item to be updated.

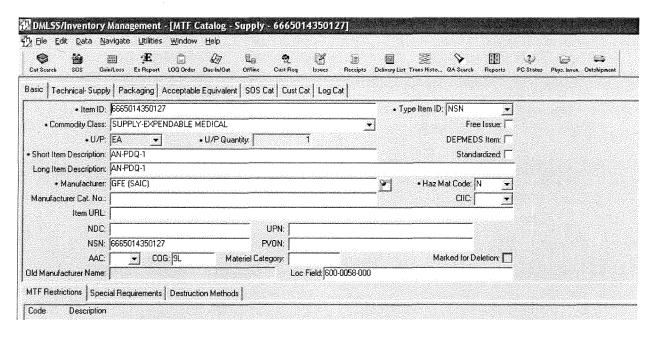


Update or GAIN an item by filling out the location, sub location, and on-hand quantity, if the CBRN equipment catalog record has already been updated from supply commodity to equipment commodity.

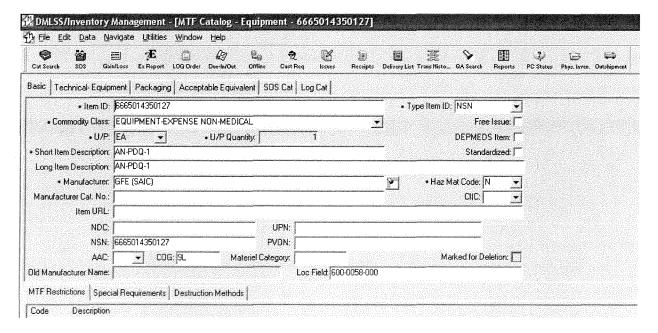
IF NOT, go the Inventory Management module and open the equipment's catalog record.



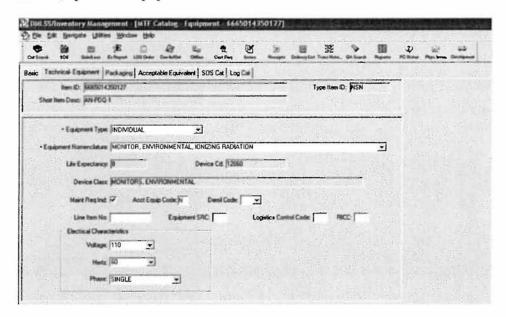
On the basic tab, change the Commodity Class from SUPPLY-EXPENDABLE MEDICAL...



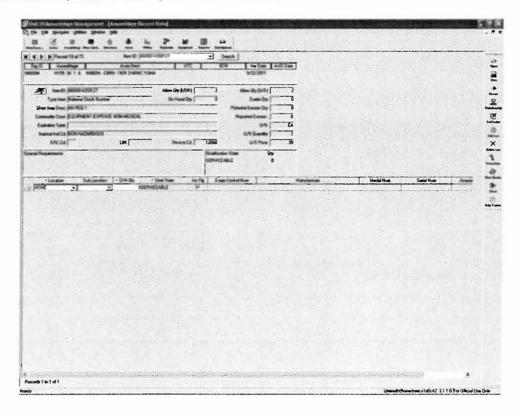
### ...to EQUIPMENT -EXPENSE NON-MEDICAL



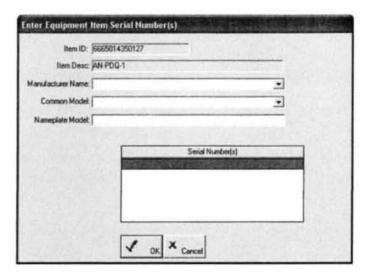
In the Technical tab, update the equipment nomenclature to the correct nomenclature.



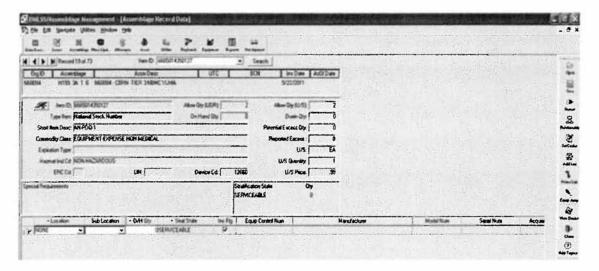
Go back to the Assemblage Management record and gain the equipment. NOTE: Equipment Control Num, Manufacturer, Serial Number, etc is now available.



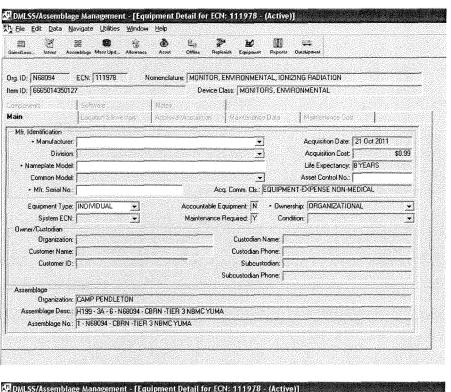
Enter/update the equipment valuation information.

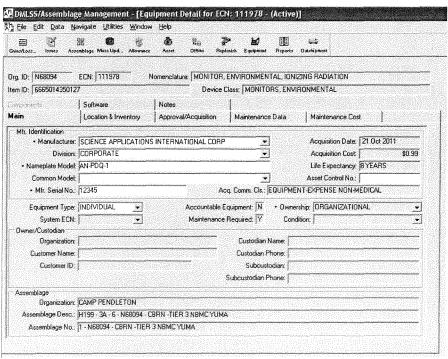


If the above process was skipped, click on Equip Jump icon on the right vertical tool bar...

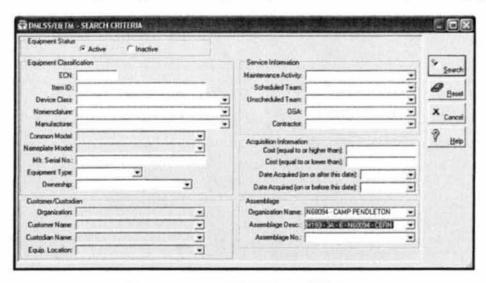


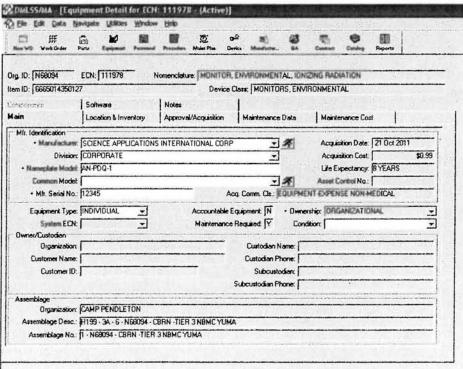
...and update the equipment information from the equipment record.



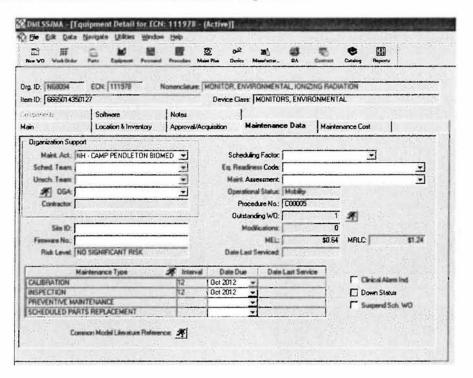


Once the above equipment gain process is completed, a maintenance record will be generated in DMLSS-AM and the Biomedical Engineering Technician (BMET) will now have visibility of the equipment.



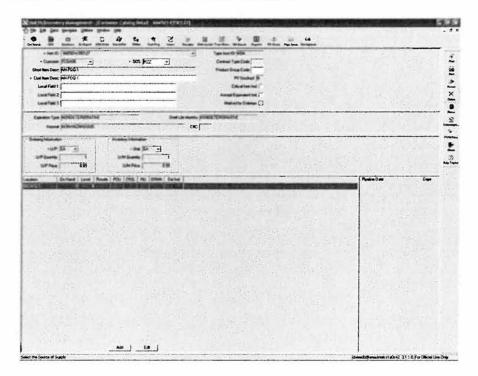


The BMET should check for the correct maintenance requirement.



### ADDITIONAL INFORMATION

To change the Commodity Class from Supply to Equipment, BIOMED is the only Customer Catalog record that can exist. If any other Customer Catalog record exists they must be marked for deletion before the Commodity Class can be changed.



To change the Commodity Class from Supply to Equipment all non-equipment, Due-In's must be resolved.

